Rule 1.126 10/6

6. (New) The pet food composition of claim 1 wherein the solid cat food is selected from the group consisting of dry kibble, moist chunk foods, moist canned cat food and cat treats.

Sub B2 7. (New) The pet food composition of claim 6 which is fortified with vitamins and micronutrients.

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on March 5, 2002, and the references cited therewith.

Claim 1 is amended, claim 5 is canceled, and claims 6-7 are added. As a result, claims 1-4 and 6-7 are pending. The above amendments did not add new matter to the application.

§103 Rejection of the Claims

Claims 1-5 were rejected under 35 USC § 103(a) as being unpatentable over Reinhart (EP 0678247 A1).

The Examiner states that Reinhart teaches a pet food composition comprising omega-6 and omega-3 fatty acids in a ratio of from 3:1 to 10:1, wherein at least 15% of the total fatty acids are omega-6 fatty acids and at least 3% of the total fatty acids are omega-3 acids. The Examiner further states that Reinhart teaches that omega-3 fatty acids are one or more compounds selected from the group consisting of eicosapentaenic acid, docosahexaenic acid and alpha-linolenic acid, and that the omega-6 fatty acids are selected from fish oil and flax. (Applicant assumes the Examiner intended to state that the omega-3 fatty acids are selected from fish oil and flax). The Examiner further states that the percentage of crude fat in Reinhart is 20 to 30% , not 7 to 14% as in Applicant's invention. The Examiner concludes that it would have been obvious to employ 7 to 14% of fat in the composition of Reinhart because the prior art amounts are similar.

Reinhart does not teach or suggest the claimed invention. Reinhart discusses a composition in which alpha-linolenic acid does not necessarily comprise the majority of the omega-3 fatty acids and in which the alpha-linolenic acid can be obtained from fish oil.

Additionally, Reinhart teaches away from the low fat composition of Applicant's invention with a total fat content in excess of 20%.

In contrast, claim 1, as amended recites a pet food composition comprising an effective inflammatory response-reducing amount, on a dry matter basis, of omega-6 and omega-3 fatty acids in a weight ratio of from about 5:1, wherein the majority of omega-3 fatty acids comprises alpha-linolenic acid derived from flax seed oil, said composition comprising from about 7 to about 14% by weight total fat and formulated as a solid cat food.

The Examiner states that the selection of the fat content is an obvious design choice. Applicant respectfully disagrees and notes that Applicant is the first to determine that flaxseed oil offers a surprisingly better alternative in a lower lipid feline diet (14% or less) because flaxseed oil shows minimal immunosuppressive activity compared to fish oil. (See specification, page 12, lines 2- 5).

Clearly, Reinhart does not recognize the problem solved in Applicant's invention and, therefore, cannot suggest the solution. Furthermore, Reinhart does not contain each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 1, as well as claims 2-4, which depend from claim 1, are patentably distinct from the references cited. The claims, viewed as a whole, are not suggested by, and not obvious under 35 U.S.C. §103(a). Reconsideration and withdrawal of this rejection is respectfully requested as it may apply to any of the pending claims.

Claims 1-5 were rejected under 35 USC § 103(a) as being unpatentable over Pscherer et al. (WO 97/19683) in view of a UC Berkeley Wellness Letter.

Applicant notes that the Examiner cited a June 1999 UC Berkeley Wellness Letter entitled, "Just the Flax Please," on the PTO-892 form that accompanied the Office Action. However, only a January 2001 UC Berkeley Wellness Letter, entitled "Cholesterol Busters" was provided with the Office Action.

Regarding the January 2001 Letter, the priority claim to U.S. Provisional Application Serial No. 60/201,029 removes this UC Berkeley Wellness Letter as a potential reference. Regarding the June 1999 Letter, Applicant has obtained and attached a copy of that Letter to this response. Applicant assumes this is the Letter the Examiner intended to provide.

The Examiner states that Pscherer teaches a lipid emulsion comprising from 35 to 65% by weight of vegetable oils which supply omega-6 fatty acids and from 5 to 20% by weight of fish oils which supply omega-3 fatty acids. The Examiner also states that Pscherer teaches that the predominant omega-6 fatty acid in the vegetable oils is alpha-linolenic acid and that the predominant omega-3 fatty acids in fish oil are eicosapentaenic and docosahexaenic acids. The Examiner admits that Pscherer does not teach the amount of total fat recited nor flaxseed as a source of linolenic acid, but that the UC Berkeley Wellness Letter teaches that flaxseed and flaxseed oil are the best source of alpha-linolenic acid. The Examiner concludes that it would have been obvious to employ flax seed oil as the source of linolenic acid in the Pscherer composition.

Pscherer teaches hydrolysis-optimized isotonic limpid emulsions comprising medium-chain triglycerides, vegetable oils as a source of omega-6 fatty acids, and fish oils as a source of omega-3 fatty acids, as well as their use for parenteral nutrition.

In contrast, claim 1, as amended, recites a pet food composition comprising an effective inflammatory response-reducing amount, on a dry matter basis, of omega-6 and omega-3 fatty acids in a weight ratio of from about 5:1, wherein the majority of omega-3 fatty acids comprises alpha-linolenic acid derived from flax seed oil, said composition comprising from about 7 to about 14% by weight total fat and formulated as a solid cat food.

Neither the 1999 or the 2001 UC Berkeley Wellness Letters overcome the deficiencies of the primary reference. The UC Wellness Berkeley Letters basically note that flaxseed oil is a good source of alpha-linolenic acid for human consumption. However, Applicant is not claiming to be the first to include alpha-linolenic acid derived from flaxseed oil in a composition. Applicant is the first, however, to provide a composition wherein the majority of omega-3 fatty acids comprises alpha-linolenic acid derived from flax seed oil, said composition comprising from about 7 to about 14% by weight total fat and formulated as a solid cat food, as recited in claim 1, as amended.

Additionally, a proper combination of references requires there be a suggestion in the primary reference, i.e., Pscherer, *as to the desirability* of having the particular feature provided in the secondary reference, and there should further be an indication of some appreciation of the

problem being solved by Applicant's invention. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988) and In Re Sang Su Lee, No. 00-1158 (Serial No. 07/631,240), (Fed. Cir.), decided January 18, 2002 (attached hereto).

There is no suggestion in Pscherer as to the desirability of using a plant source, such as flaxseed oil, for alpha-linolenic acid. Furthermore, since the total fat content is not discussed in Pscherer, there is clearly not any recognition that flaxseed oil is a better source for alpha-linolenic acid in a low fat feline diet. Clearly, Pscherer does not recognize the problem solved by Applicant's invention and so cannot suggest the solution.

The combination suggested by the Examiner does not teach each and every element of Applicant's claims. Further, the additional elements recited in dependent claims 2-4 cannot by themselves be rendered obvious over the cited references if the independent claim from which the claim depends is determined to be nonobvious. As claims 2-4 depend from and further define claim 1, claims 2-4 are believed to be allowable.

The references neither independently, or combined, contain each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 1, as well as claims 2-4, which depend from claim 1, are patentably distinct from the references cited. The claims, viewed as a whole, are not suggested by, and not *prima facie* obvious over the disclosures of the cited documents. Reconsideration and withdrawal of this rejection is respectfully requested as it may apply to any of the pending claims.

Conclusion

Applicant respectfully submits that the claims (1-4 and 6-7) are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Barbara Clark at 515-233-3865 or the below-signed attorney at 612-359-3265 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

MICHAEL GRIFFIN HAYEK ET AL.

By their Representatives,

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Date 8-5-02 By _____

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 5th day of August, 2002.

Dawn M Poole
Name

Dawn M. Poole
Signature

Docket No. 01448.038US1
WD # 455076.wpd

Iams Ref. No.: IAM 0618PA

Clean Version of Pending Claims

PET FOOD COMPOSITION FOR REDUCING INFLAMMATORY RESPONSE IN CATS
Applicant: Michael Griffin Hayek et al.
Serial No.: 09/845,941

1. A pet food composition comprising an effective inflammatory response-reducing amount, on a dry matter basis, of omega-6 and omega-3 fatty acids in a weight ratio of from about 5:1, wherein the majority of omega-3 fatty acids comprises alpha-linolenic acid derived from flaxseed oil, said composition comprising from about 7 to about 14% by weight total fat, which composition is formulated as a solid cat food.

2. The pet food composition of claim 1 in which at least about 20 wt% of the total fatty acids are omega-6 fatty acids.

3. The pet food composition of claim 1 in which at least about 4 wt% of the total fatty acids are omega-3 fatty acids.

4. The pet food composition of claim 1 in which said omega-3 fatty acids further comprise eicosapentaenoic acid, docosahexaenoic acid, or combinations thereof.

6. The pet food composition of claim 1 wherein the solid cat food is selected from the group consisting of dry kibble, moist chunk foods, moist canned cat food and cat treats.

7. The pet food composition of claim 6 which is fortified with vitamins and micronutrients.

University of California, Berkeley
Wellness Letter
THE NEWSLETTER OF NUTRITION, FITNESS & STRESS MANAGEMENT

Volume 15, Issue 9 June 1999 *From the School of Public Health*

New study tarnishes chromium

We've always had doubts about the benefits—and more importantly, the safety—of chromium supplements. Millions currently take chromium picolinate in the hope of preventing or reversing diabetes, reducing blood cholesterol, and building muscle. Weight loss is even touted as one of its benefits. But the evidence is mounting that these supplements can do more harm than good.

Chromium is an essential trace mineral found in a wide variety of foods. It is important in the burning of carbohydrates and fats in the body, and helps insulin do its work of making blood sugar (glucose, our basic fuel) available to cells. Nobody is sure how much chromium we need to stay healthy, but some experts worry that we don't get enough. Chromium in food is not easily absorbed by the body. Chromium picolinate—the form of the mineral commonly sold as a supplement—is more easily absorbed.

Three years ago a laboratory study from Dartmouth College showed that chromium picolinate could damage the genetic material of hamster cells. This raised the question of whether it might cause cancer in humans. The response from the supplements industry was indignant: "bad science," they cried. It's true that it was only a lab study, and that what happens to hamster cells in a test tube might not happen to human cells in the body. But then again, this kind of genetic damage can be a warning signal.

Now a new study conducted by Dr. John Vincent at the University of Alabama at Tuscaloosa shows that chromium picolinate enters the cells directly and stays there—where it can cause problems. In fact, the chromium picolinate reacts with vitamin C and other antioxidants in the cells to produce a "reduced" form of chromium capable of causing mutations in DNA, the genetic material. It's the combination of chromium and picolinate (particularly the reduced form) that can produce dangerous compounds—not the chromium alone. Moreover, the picolinate eventually breaks off and itself has adverse effects.

Words to the wise: *There's little evidence that chromium deficiency is widespread. Some very preliminary research suggests that chromium picolinate can reduce blood sugar in people with Type 2 diabetes, the most common form of the disease. But that's a far cry from a reliable treatment for diabetes, which is not a chromium-deficiency disease. There is no good evidence backing chromium picolinate as a weight-loss aid, a muscle-builder, or a way to reduce blood cholesterol levels. This new evidence does suggest that it may have serious side effects. Nobody should take chromium picolinate, especially not young people.*

Wellness facts

■ The American Academy of Pediatrics no longer recommends routine circumcision for male infants. The AAP finds that there is no good reason to circumcise a child. While circumcision may slightly reduce the risk of a urinary tract infection in infancy and of penile cancer later in life, both of these conditions are rare, and the risk for either extremely low anyway. The AAP urges parents to circumcise a son for religious or cultural reasons only. Local anesthesia is recommended for the baby.

■ Dental amalgam—silver fillings—has been blamed for many health ills, but has repeatedly been acquitted by scientific studies. Recently, amalgam has been investigated as a potential cause of Alzheimer's disease. A new study in the *Journal of the American Dental Association* finds no association between amalgam and Alzheimer's. It's true that fillings contain mercury, but the study showed that the restorations don't affect the level of mercury in the brain.

■ Folic acid and vitamin B_{12} may help keep your hearing keen as you grow older. As we previously reported, these B vitamins may protect against heart disease. Now a recent study in the *Journal of Clinical Nutrition* finds that women in their sixties with normal hearing ability had higher blood levels of folic acid and B_{12} (from diet or supplements) than those with hearing dysfunction. The study was small, but provides an interesting new avenue for research.

Does smart aspirin pass the test?

A new form of aspirin, called a COX-2 inhibitor and available only by prescription, is now on the market. Here's how to thread your way through the chemistry and the claims and counterclaims.

Aspirin is a miracle drug—a cheap, effective, nonaddicting pain reliever that quells inflammation and fever, helps prevent heart attacks, and may well have other long-term benefits, including reducing colon cancer risk. It is one of the nonsteroidal anti-inflammatory drugs, or NSAIDs. The other over-the-counter NSAIDs are ibuprofen (such as Advil and Motrin) and naproxen sodium (Aleve); these are also sold by prescription. NSAIDs act to prevent the body from manufacturing certain substances called prostaglandins. Prostaglandins have many functions: some cause pain and inflammation, but others protect the lining of the stomach. Thus, in blocking the beneficial prostaglandins as well as the ones that cause pain, NSAIDs can cause stomach upset or produce

(continued on page 2)

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gastrointestinal bleeding and ulcers in susceptible people, particularly when taken over long periods.

Why "COX-2 inhibitor"?

Recent discoveries have made it possible to design a "smart" aspirin that sidesteps the stomach damage. Two enzymes in the body, known as COX-1 and COX-2, make prostaglandins. COX-1 makes those that protect the stomach lining and clot the blood; COX-2 produces those that cause pain and inflammation. The new drug blocks the COX-2 enzyme but not COX-1. Thus it relieves pain and inflammation with a much lower incidence of gastrointestinal side effects. One COX-2 inhibitor is now on the market: Celebrex (generic name, celeboxib; formerly called Celebra). Others, such as Vioxx and Mobic, are still under review.

COX-2 inhibitors are prescription drugs and under patent, so no generics are available. Celebrex costs $1.50 per 100-milligram pill and $2.50 for 200 milligrams, the maximum daily dose. If you need the maximum dose every day for pain, that's more than $900 a year—a pretty high price tag.

Who should use them

COX-2 inhibitors are approved only for rheumatoid arthritis and osteoarthritis—so if you have been diagnosed with either, you might be a candidate. The first line of defense against the pain of osteoarthritis, though, is usually not an NSAID, but acetaminophen (Tylenol, Panadol, Anacin-3, and generics). Acetaminophen, which relieves pain without gastrointestinal side effects, remains a useful drug and should not be discarded in favor of something so much more expensive. Clinical trials did not compare Celebrex to over-the-counter pain relievers, only to prescription NSAIDs. Fearing the economic effects of COX-2 inhibitors, Tylenol has mounted a huge advertising campaign against them.

If you are already taking NSAIDs to relieve arthritis, you might want to talk with your doctor about Celebrex. While the FDA considers it safe and effective, Celebrex is quite new and could turn out to have unexpected side effects. It may interact with certain drugs. You should discuss all this with your doctor.

A COX-2 inhibitor is not a substitute for the low-dose aspirin used to prevent heart attacks or for any over-the-counter pain reliever that you use only occasionally. Low-dose aspirin does not damage the stomach lining, and *only* aspirin (not Celebrex, not ibuprofen, and not acetaminophen) has the desirable blood-thinning effects that help prevent heart attacks.

Keep in mind: *COX-2 inhibitors may turn out to be ideal drugs, with many of aspirin's immediate and long-term benefits and none of its drawbacks. You should be able to take COX-2 inhibitors for arthritis and low-dose aspirin for your heart, if you need both drugs. Follow your doctor's advice. If you have arthritis and are doing well on acetaminophen, aspirin, or another NSAID, there is no reason to switch. Pregnant and potentially pregnant women should not take COX-2 inhibitors.*

Doctors "supplement" their income

"My eye doctor is recommending and selling spray vitamin supplements as a way to reduce the risk of macular degeneration. The price per one-ounce bottle is $24... I'm trying to decide whether this is a good thing or if the doctor is just trying to make money on the side." This question came from a reader in Arizona.

Yes, obviously, the doctor is making money on the side. The supplement in question is an oral spray containing the two carotenoids lutein and zeaxanthin, which occur naturally in many foods and are thought to be protective against macular degeneration, an eye condition that can cause serious vision loss or even blindness in older people. In our January issue we discussed the importance of eating foods rich in carotenoids as a possible hedge against macular degeneration.

The physician selling this supplement to our reader is an M.D., certified by the American Board of Ophthalmology. What are the problems, then? First, no study has ever shown that taking lutein and zeaxanthin in supplement form will do anything to help your eyes, let alone that an oral spray is the right way to deliver these phytochemicals. Second, there's no proof that this supplement (manufactured by BioMax, a San Diego company) contains much, or any, lutein or zeaxanthin. "We make no claims to treatment of disease or illness," its brochure says in very fine print. But in la type, it claims to keep vision healthy, to protect against mac degeneration and cataracts, and to "protect the lungs." Nothing o the sort has ever been demonstrated.

Medical ethics dumped overboard?

Is it ethical for a doctor to sell supplements to patients? Even the most honest physician might be tempted to prescribe drugs or supplements that the patient didn't really need if it meant a nice profit—so it's a clear case of conflict of interest. Even the best-informed, most independent-minded patients trust their doctors and wish to follow medical advice. Patients less informed, or those in awe of doctors, might feel too intimidated to say no.

According to the *Nutrition Business Journal*, "over $350 million of dietary supplements and other natural products are currently sold directly to conventional and alternative medical practitioners, who in turn sell an estimated $700 million in natural

UC BERKELEY WELLNESS LETTER

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other benefits, too. Becoming active may be the most important step you can take.

✓ Do exercises to strengthen your back. For starters, see our articles on stretching (December 1998) and sit-ups (June 1998). Both types of exercise are excellent for the back. Or get a referral to a physical therapist who can teach you beneficial exercises for your back.

✓ If you smoke, quit. Smoking aggravates back pain.

✓ Wear comfortable shoes that provide good support. Avoid high heels.

✓ If you have to stand for long periods, try resting one foot on a stool.

(In an upcoming issue, the *Wellness Letter* will discuss lumbar pillows, mattresses, and other gear available at back shops.)

Just the flax facts, please

Should you eat flaxseed? Use flaxseed oil for cooking and salads? Take flaxseed supplements? Will flaxseed in any form lower blood cholesterol and prevent heart attacks? Is flax more powerful than other seeds and oils? Flax is a particularly interesting plant that is under study at the National Cancer Institute and other research centers.

The flax plant, an old friend of humanity, yields the fiber from which linen is woven, as well as seeds and oil. The oil, also called linseed oil, has many industrial uses—as an ingredient in paints, varnishes, and linoleum, and as a finishing oil for wood furniture. It also comes in an edible form, sold mostly at health-food stores. Like olive, canola, and most other plant-derived oils, it is highly unsaturated and is thus a healthful choice to replace saturated fats in animal products. Flaxseed, from which the oil is extracted, can be eaten whole or ground into flour.

Some people now believe that flaxseed and its oil are special—that their health effects are greater than those of other seeds and oils. The background is complex.

The alpha-linolenic story: oil

Flaxseed and flaxseed oil are by far the best food source of alpha-linolenic acid. This is one of the essential fatty acids—that is, it's essential for life, and we must consume it in foods, because our bodies cannot manufacture it. Essential fatty acids are important for cell membranes, blood pressure regulation, and other functions. Alpha-lino*lenic* acid is an omega-3, similar to some of the fatty acids in fish oil. (Another essential fatty acid is lino*leic* acid, an omega-6, found in most vegetable oils, which has a different function in the body.) Consumption of fish and fish oil has been linked to a reduced risk of dying from heart disease, though it is unclear how it does this—see *Wellness Letter*, March 1999.

But alpha-linolenic acid is not identical to the omega-3 fatty acids found in fish oil. The body does convert alpha-linolenic acid from plant foods into those omega-3s, but very slowly and inefficiently. It's a longer process than getting the omega-3s directly from fish.

Flaxseed may be the best food source of alpha-linolenic acid, but the evidence for specific heart benefits from flaxseed is very thin. A few population studies have linked a high *total* intake of alpha-linolenic acid with a reduced risk of heart disease and/or death from heart disease. And recently a French study found that a "Mediterranean diet" relatively rich in alpha-linolenic acid greatly reduced the risk of second heart attacks (see *Wellness Letter*, May 1999). However, the alpha-linolenic acid in that study did not come from flaxseed, but from a canola-oil margarine. Besides flaxseed and canola oil, alpha-linolenic acid is also found in soybean oil and walnuts. *You don't have to consume flaxseed to get alpha-linolenic acid.* If flaxseed oil (or the seeds, which contain the oil) does lower blood cholesterol, that should come as no big surprise, since any unsaturated oil, particularly if substituted for saturated fats, will do so.

The lignan story: seeds

Besides alpha-linolenic acid, flaxseed is also rich in certain phytochemicals (plant chemicals). Notably, it is the richest source of lignans, which provide fiber. Lignans are also a type of phytoestrogen (isoflavonoids are another type). In the process of digestion, bacteria convert lignans into estrogen-like substances called enterodiol and enterolactone. These may have anti-tumor effects. Phytoestrogens are also found in other plants, including soy, certain herbs, whole grains, and other seeds. Lignans and other flaxseed components may also have antioxidant properties—that is, they may reduce the activity of free radicals, which cause damage at the cellular level. Studies have shown that flaxseed can reduce tumors in lab animals. So far there's no convincing evidence of a similar action in humans, though some ongoing studies may provide answers. In addition, lignans may play some role in lowering cholesterol and possibly in maintaining bone density. Flaxseed oil usually does not contain lignans, though some processors do add some lignans back into the oil.

It is increasingly difficult to single out any one plant food as unique or miraculous. All plant foods have good things to offer. Garlic and onions apparently have a range of beneficial chemicals; so does tea. So do the herbs we use for flavoring, such as rosemary, thyme, parsley, sage, and so forth. Broccoli and other cruciferous vegetables have anticancer potential. Canola and olive oil and other highly unsaturated oils help lower blood cholesterol. So do oats, which contain the same kind of fiber found in flaxseed.

Adding flaxseed to your diet

It certainly can't hurt to add flaxseed and its oil to a healthy diet—one based on fruits, vegetables, whole grains, nonfat dairy products, and small amounts of fish and meat, and thus low in saturated fat and cholesterol. But adding flaxseed to a poor diet is not likely to help much.

Flaxseed flour or ground or whole flaxseeds can be found in some breads, muffins, cereals, and breakfast bars, particularly in health-food stores. Flaxseeds have a pleasant, nutty flavor and are tasty sprinkled on salads, cooked vegetables, or cereals. (However, unless the seeds are well chewed or ground, they simply pass through the body.) You may want to combine flaxseed flour with wheat flour for baking. The seeds and the oil spoil quickly: the oil comes in dark bottles to extend its shelf life; the oil, once opened, as well as ground flaxseed and flour, should be refrigerated. And the oil is expensive.

Two cautions: in rare instances people may have allergic reactions to flaxseed (anaphylactic shock, as from bee stings or nuts). Flaxseed is high in fiber, so increase water intake along with it.

And supplements too? *Flaxseed supplements, which usually contain ground seeds plus vitamin E, are gaining popularity. We do recommend taking supplemental vitamin E (200 to 800 IU daily). But skip the flaxseed capsules. If you want to make flaxseed part of your diet, consume the oil or the flour, not the supplements.*

Unit d Stat s Court of Appeals for th Fed ral Circuit

00-1158
(Serial No. 07/631,240)

IN RE SANG SU LEE

Richard H. Stern, of Washington, DC, argued for Sang Su Lee. With him on the brief was Robert E. Bushnell.

Sidney O. Johnson, Jr., Associate Solicitor, of Arlington, Virginia, argued for the Director of the U.S. Patent and Trademark Office. With him on the brief were John M. Whealan, Solicitor, and Raymond T. Chen, Associate Solicitor. Of counsel were Maximilian R. Peterson and Mark Nagumo, Associate Solicitors.

Appealed from: Patent & Trademark Office
Board of Patent Appeals and Interferences

United States Court of Appeals for th Federal Circuit

00-1158
(Serial No. 07/631,240)

IN RE SANG-SU LEE

DECIDED: January 18, 2002

Before NEWMAN, CLEVENGER, and DYK, Circuit Judges.

NEWMAN, Circuit Judge.

Sang-Su Lee appeals the decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office, rejecting all of the claims of Lee's patent application Serial No. 07/631,210 entitled "Self-Diagnosis and Sequential-Display Method of Every Function."[1] We vacate the Board's decision for failure to meet the adjudicative standards for review under the Administrative Procedure Act, and remand for further proceedings.

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1 Ex parte Lee, No. 1994-1989 (Bd. Pat. App. & Int. Aug. 30, 1994; on reconsid'n Sept. 29, 1999).

The Prosecution R cord

Mr. Lee's patent application is directed to a method of automatically displaying the functions of a video display device and demonstrating how to select and adjust the functions in order to facilitate response by the user. The display and demonstration are achieved using computer-managed electronics, including pulse-width modulation and auto-fine-tuning pulses, in accordance with procedures described in the specification. Claim 10 is representative:

> 10. A method for automatically displaying functions of a video display device, comprising:
>
> determining if a demonstration mode is selected;
>
> if said demonstration mode is selected, automatically entering a picture adjustment mode having a picture menu screen displaying a list of a plurality of picture functions; and
>
> automatically demonstrating selection and adjustment of individual ones of said plurality of picture functions.

The examiner rejected the claims on the ground of obviousness, citing the combination of two references: United States Patent No. 4,626,892 to Nortrup, and the Thunderchopper Helicopter Operations Handbook for a video game. The Nortrup reference describes a television set having a menu display by which the user can adjust various picture and audio functions; however, the Nortrup display does not include a demonstration of how to adjust the functions. The Thunderchopper Handbook describes the Thunderchopper game's video display as having a "demonstration mode" showing how to play the game; however, the Thunderchopper Handbook makes no mention of the adjustment of picture or audio functions. The examiner held that it would have been obvious to a person of ordinary skill to combine the teachings of these references to produce the Lee system.

Lee appealed to the Board, arguing that the Thunderchopper Handbook simply explained how to play the Thunderchopper game, and that the prior art provided no

teaching or motivation or suggestion to combine this reference with Nortrup, or that such combination would produce the Lee invention. The Board held that it was not necessary to present a source of a teaching, suggestion, or motivation to combine these references or their teachings. The Board stated:

> The conclusion of obviousness may be made from common knowledge and common sense of a person of ordinary skill in the art without any specific hint or suggestion in a particular reference.

Board op. at 7. The Board did not explain the "common knowledge and common sense" on which it relied for its conclusion that "the combined teachings of Nortrup and Thunderchopper would have suggested the claimed invention to those of ordinary skill in the art."

Lee filed a request for reconsideration, to which the Board responded after five years. The Board reaffirmed its decision, stating that the Thunderchopper Handbook was "analogous art" because it was "from the same field of endeavor" as the Lee invention, and that the field of video games was "reasonably pertinent" to the problem of adjusting display functions because the Thunderchopper Handbook showed video demonstrations of the "features" of the game. On the matter of motivation to combine the Nortrup and Thunderchopper references, the Board stated that "we maintain the position that we stated in our prior decision" and that the Examiner's Answer provided "a well reasoned discussion of why there is sufficient motivation to combine the references." The Board did not state the examiner's reasoning, and review of the Examiner's Answer reveals that the examiner merely stated that both the Nortrup function menu and the Thunderchopper demonstration mode are program features and that the Thunderchopper mode "is user-friendly" and it functions as a tutorial, and that it would have been obvious to combine them.

Lee had pressed the examiner during prosecution for some teaching, suggestion, or motivation in the prior art to select and combine the references that were relied on to show obviousness. The Examiner's Answer before the Board, plus a Supplemental Answer, stated that the combination of Thunderchopper with Nortrup "would have been obvious to one of ordinary skill in the art since the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software," and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial." The Board adopted the examiner's answer, stating "the examiner has provided a well reasoned discussion of these references and how the combination of these references meets the claim limitations." However, perhaps recognizing that the examiner had provided insufficient justification to support combining the Nortrup and Thunderchopper references, the Board held, as stated supra, that a "specific hint or suggestion" of motivation to combine was not required.

This appeal followed.

Judicial Review

Tribunals of the PTO are governed by the Administrative Procedure Act, and their rulings receive the same judicial deference as do tribunals of other administrative agencies. Dickinson v. Zurko, 527 U.S. 150, 50 USPQ2d 1930 (1999). Thus on appeal we review a PTO Board's findings and conclusions in accordance with the following criteria:

5 U.S.C. §706(2) The reviewing court shall--

> (2) hold unlawful and set aside agency actions, findings, and conclusions found to be--

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> ****
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute;

For judicial review to be meaningfully achieved within these strictures, the agency tribunal must present a full and reasoned explanation of its decision. The agency tribunal must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application of the law to the found facts. The Court has often explained:

> The Administrative Procedure Act, which governs the proceedings of administrative agencies and related judicial review, establishes a scheme of "reasoned decisionmaking." Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational.

Allentown Mack Sales and Service, Inc. v. National Labor Relations Bd., 522 U.S. 359, 374 (1998) (citation omitted). This standard requires that the agency not only have reached a sound decision, but have articulated the reasons for that decision. The reviewing court is thus enabled to perform meaningful review within the strictures of the APA, for the court will have a basis on which to determine "whether the decision was based on the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971). Judicial review of a Board decision denying an application for patent is thus founded on the obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based, accompanied by the agency's reasoning in reaching its conclusions. See In re Zurko, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (review is on the administrative record); In re Gartside, 203 F.3d 1305, 1314, 53 USPQ2d 1769, 1774 (Fed. Cir. 2000) (Board decision "must be justified within the four

corners of the record").

As applied to the determination of patentability vel non when the issue is obviousness, "it is fundamental that rejections under 35 U.S.C. §103 must be based on evidence comprehended by the language of that section." In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983). The essential factual evidence on the issue of obviousness is set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors).

"The factual inquiry whether to combine references must be thorough and searching." Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding'") (quoting C.R. Bard, Inc., v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998)); In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction

of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) ("'teachings of references can be combined only if there is some suggestion or incentive to do so.'") (emphasis in original) (quoting ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

The need for specificity pervades this authority. See, e.g., In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"); In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references").

With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to

render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion.

Deferential judicial review under the Administrative Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings. To the contrary, the Administrative Procedure Act reinforces this obligation. See, e.g., Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 43 (1983) ("the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'") (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)); Securities & Exchange Comm'n v. Chenery Corp., 318 U.S. 80, 94 (1943) ("The orderly function of the process of review requires that the grounds upon which the administrative agency acted are clearly disclosed and adequately sustained.").

In its decision on Lee's patent application, the Board rejected the need for "any specific hint or suggestion in a particular reference" to support the combination of the Nortrup and Thunderchopper references. Omission of a relevant factor required by precedent is both legal error and arbitrary agency action. See Motor Vehicle Manufacturers, 463 U.S. at 43 ("an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem"); Mullins v. Department of Energy, 50 F.3d 990, 992 (Fed. Cir. 1995) ("It is well established that agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action."). As discussed in National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp., 817 F.2d 74, 75 (9th Cir. 1987), an agency is "not free to refuse to follow circuit precedent."

The foundation of the principle of judicial deference to the rulings of agency tribunals is that the tribunal has specialized knowledge and expertise, such that when reasoned findings are made, a reviewing court may confidently defer to the agency's application of its knowledge in its area of expertise. Reasoned findings are critical to the performance of agency functions and judicial reliance on agency competence. See Baltimore and Ohio R. R. Co. v. Aberdeen & Rockfish R. R. Co., 393 U.S. 87, 91-92 (1968) (absent reasoned findings based on substantial evidence effective review would become lost "in the haze of so-called expertise"). The "common knowledge and common sense" on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in Zurko, 258 F.3d

at 1385, 59 USPQ2d at 1697, that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.'" The Board's findings must extend to all material facts and must be documented on the record, lest the "haze of so-called expertise" acquire insulation from accountability. "Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority. See Allentown Mack, 522 U.S. at 376 ("Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the Board must be required to apply in fact the clearly understood legal standards that it enunciates in principle . . . .")

The case on which the Board relies for its departure from precedent, In re Bozek, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969), indeed mentions "common knowledge and common sense," the CCPA stating that the phrase was used by the Solicitor to support the Board's conclusion of obviousness based on evidence in the prior art. Bozek did not hold that common knowledge and common sense are a substitute for evidence, but only that they may be applied to analysis of the evidence. Bozek did not hold that objective analysis, proper authority, and reasoned findings can be omitted from Board decisions. Nor does Bozek, after thirty-two years of isolation, outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and Patent Appeals that determination of patentability must be based on evidence. This court has remarked, in Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1421 (Fed. Cir. 1999), that Bozek's reference to common knowledge "does not in and of itself make it so" absent evidence of such knowledge.

The determination of patentability on the ground of unobviousness is ultimately one of judgment. In furtherance of the judgmental process, the patent examination procedure serves both to find, and to place on the official record, that which has been considered with respect to patentability. The patent examiner and the Board are deemed to have experience in the field of the invention; however, this experience, insofar as applied to the determination of patentability, must be applied from the viewpoint of "the person having ordinary skill in the art to which said subject matter pertains," the words of section 103. In finding the relevant facts, in assessing the significance of the prior art, and in making the ultimate determination of the issue of obviousness, the examiner and the Board are presumed to act from this viewpoint. Thus when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record. The failure to do so is not consistent with either effective administrative procedure or effective judicial review. The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies.

Alternative Grounds

At oral argument the PTO Solicitor proposed alternative grounds on which this court might affirm the Board's decision. However, as stated in Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962), "courts may not accept appellate counsel's post hoc rationalization for agency action." Consideration by the appellate tribunal of new agency justifications deprives the aggrieved party of a fair opportunity to support its position; thus review of an administrative decision must be made on the grounds relied on by the agency. "If those grounds are inadequate or improper, the court is powerless to

affirm the administrative action by substituting what it considers to be a more adequate or proper basis." Securities & Exchange Comm'n v. Chenery Corp., 332 U.S. 194, 196 (1947). As reiterated in Federal Election Comm'n v. Akins, 524 U.S. 11, 25 (1998), "If a reviewing court agrees that the agency misinterpreted the law, it will set aside the agency's action and remand the case -- even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a different reason." Thus we decline to consider alternative grounds that might support the Board's decision.

Further Proceedings

Sound administrative procedure requires that the agency apply the law in accordance with statute and precedent. The agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action. In Radio-Television News Directors Ass'n v. FCC, 184 F.3d 872 (D.C. Cir. 1999) the court discussed the "fine line between agency reasoning that is 'so crippled as to be unlawful' and action that is potentially lawful but insufficiently or inappropriately explained," quoting from Checkosky v. Securities & Exch. Comm'n, 23 F.3d 452, 464 (D.C. Cir. 1994); the court explained that "[i]n the former circumstance, the court's practice is to vacate the agency's order, while in the latter the court frequently remands for further explanation (including discussion of the relevant factors and precedents) while withholding judgment on the lawfulness of the agency's proposed action." Id. at 888. In this case the Board's analysis of the Lee invention does not comport with either the legal requirements for determination of obviousness or with the requirements of the Administrative Procedure Act that the agency tribunal set forth the findings and

explanations needed for "reasoned decisionmaking." Remand for these purposes is required. See Overton Park, 401 U.S. at 420-221 (remanding for further proceedings appropriate to the administrative process).

VACATED AND REMANDED